NIV - Non-Invasive Ventilation

Mask Ventilation

Operating Instructions Addendum
Evita 4 as of Software 4.n
Evita 2 dura as of Software 4.n

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Important Safety Information

Operator's Responsibility for Patient Safety

For correct and effective use of the product and in order to avoid hazards it is mandatory to carefully read and to observe all portions of this manual.
The design of the equipment, the accompanying literature, and the labeling on the equipment take into consideration that the purchase and use of the equipment are restricted to trained professionals, and that certain inherent characteristics of the equipment are known to the trained operator. Instructions, warnings, and caution statements are limited, therefore, largely to the specifics of the Dräger design.
This publication excludes references to various hazards which are obvious to a medical professional and operator of this equipment, to the consequences of product misuse, and to potentially adverse effects in patients with abnormal conditions. Product modification or misuse can be dangerous. Dräger Medical, Inc. disclaims all liability for the consequences of product alterations or modifications, as well as for the consequences which might result from the combination of this product with other products whether supplied by Dräger or by other manufacturers if such a combination is not endorsed by Dräger Medical, Inc.

Patient monitoring

The operators of the ventilator system must recognize their responsibility for choosing appropriate safety monitoring that supplies adequate information on equipment performance and patient condition. Patient safety may be achieved through a wide variety of different means ranging from electronic surveillance of equipment performance and patient condition to simple, direct observation of clinical signs. The responsibility for the selection of the best level of patient monitoring lies solely with the equipment operator.

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Dräger Medical, Inc. shall not be liable for, nor shall buyer be entitled to recover any special incidental, or consequential damages or for any liability incurred by buyer to any third party in any way arising out of or relating to the goods.

Warranty

All Dräger products are guaranteed to be free of defects for a period of one year from date of delivery.
The following are exceptions to this warranty:

1. The defect shall be a result of workmanship or material. Defects caused by misuse, mishandling, tampering, or by modifications not authorized by Dräger Medical, Inc. or its representatives are not covered.
2. Rubber and plastic components and materials are warranted to be free of defects at time of delivery.

Any product which proves to be defective in workmanship or material will be replaced, credited, or repaired with Dräger Medical, Inc. holding the option. Dräger Medical, Inc. is not responsible for deterioration, wear, or abuse. In any case, Dräger Medical, Inc. will not be liable beyond the original selling price.

Application of this warranty is subject to the following conditions:

1. Dräger Medical, Inc. or its authorized representative must be promptly notified, in writing, upon detection of the defective material or equipment.
2. Defective material or equipment must be returned, shipping prepaid, to Dräger or its authorized representative.
3. Examination by Dräger or its authorized representative must confirm that the defect is covered by the terms of this warranty.
4. Notification in writing, of defective material or equipment must be received by Dräger or its authorized representative no later than two (2) weeks following expiration of this warranty.

The above is the sole warranty provided by Dräger Medical, Inc. No other warranty expressed or implied is intended. Representatives of Dräger are not authorized to modify the terms of this warranty.

Dräger Medical, Inc., Telford, PA

Definitions

WARNING !

A WARNING statement refers to conditions with a possibility of personal injury if disregarded.

CAUTION !

A CAUTION statement designates the possibility of damage to equipment if disregarded.

NOTE: A NOTE provides additional information intended to avoid inconveniences during operation.

Inspection	examination of actual condition
Service	measures to maintain specified condition
Repair	measures to restore specified condition
Maintenance	inspection, service, and repair, where necessary
Preventive Maintenance	maintenance measures at regular intervals

Typing conventions in this manual
Display messages are printed in bold, e. g:

!!! Fail to cycle

Screen keys and other controls are indicated as »**Control**«, e.g:

»⏻ **Standby**«

Summary of WARNINGS and CAUTIONS

General CAUTIONS and WARNINGS

WARNING !

**Strictly follow this Operator's Instruction Manual !
Any use of the ventilator this option is intended for requires full understanding and strict observation of all portions of these instructions as well as the Operating Instructions of the Evita 4 or Evita 2 dura ventilators, respecitvely. The equipment is only to be used for the purpose specified under "Intended Use" (see page 9). Observe all WARNINGS and CAUTIONS as rendered throughout the manuals and on labels on the equipment.**

WARNING !

The Evita 4 and Evita 2 dura intesive care ventilators must only be used under the supervision of qualified medical personnel in order to provide immediate corrective action in case of a malfunction.

WARNING !

For intended use of the Evita 4 and Evita 2 dura ventilators with intubated patients and restrictions of use, always refer to the ventilators' respective (main) Operating Instruction Manuals.

**CAUTION !
Restriction of Distribution**

Federal Law and Regulations in the United States and Canada restrict this device to sale by or on the order of a physician.
Device for use only in health care facilities and only by persons with specific training and experience in the use of the device.

**CAUTION !
Maintenance**

In case of malfunction of this device, you should contact your local DrägerService or a Factory Authorized Technical Service Center.
Evita 4 and Evita 2 dura ventilators must be inspected and serviced (preventive maintenance) by factory trained and authorized technical service personnel at regular 6 month intervals. A record must be kept on this preventive maintenance. We recommend obtaining a service contract through your vendor.
Maintenance or repair of Evita ventilators should be performed by Dräger authorized technical service personnel only

Precautions during use of NIV

WARNING !

**Deadspace will increase when using a mask.
Observe mask manufacturers data on dead space.**

WARNING !

Switching to operation mode "mask" when ventilating an intubated patient, could result in inadequate monitoring and put intubated patients at risk.

WARNING !

Always check alarm limits after switching from "mask" to "tube" mode.

WARNING !

When ventilating with a mask, avoid high airway pressures. Danger of aspiration.

WARNING !

Switch off alarms only when patient safety is not compromised by deactivated alarms. The operator of the ventilator must still assume full responsibility for proper ventilation of the patient.

WARNING !

Always check alarm limits when switching from »Mask« to »Tube«!

Intended Use

NIV - Non-invasive Ventilation

Non-invasive ventilation is an option for ventilation via a nasal or face mask supporting non-invasive respiratory therapies. NIV adds the choice between mask ventilation and ventilation of intubated patients.
The NIV option extends the range of applications for Evita 4 and Evita 2 dura ventilators as of software 4.n.

WARNING !

The Evita 4 and Evita 2 dura intensive care ventilators must only be used under the supervision of qualified medical personnel in order to provide immediate corrective action in case of a malfunction.

WARNING !

For intended use of the Evita 4 and Evita 2 dura ventilators with intubated patients and restrictions of use, always refer to the ventilators' respective (main) Operating Instruction Manuals.

Installing the NIV-Option

WARNING !

Installation of the NIV option should only be performed by factory trained and authorized service personnel following the respective installation documentation.

Using NIV

WARNING !

Deadspace will increase when using a mask.
Observe mask manufacturers data on dead space.

WARNING !

Switching to operation mode "mask" when ventilating an intubated patient, could result in inadequate monitoring and put intubated patients at risk.

WARNING !

Always check alarm limits after switching from "mask" to "tube" mode.

WARNING !

When ventilating with a mask, avoid high airway pressures.
Danger of aspiration.

In »**Mask**« application mode, all ventilation modes are available with the exception of »**ILV**«.

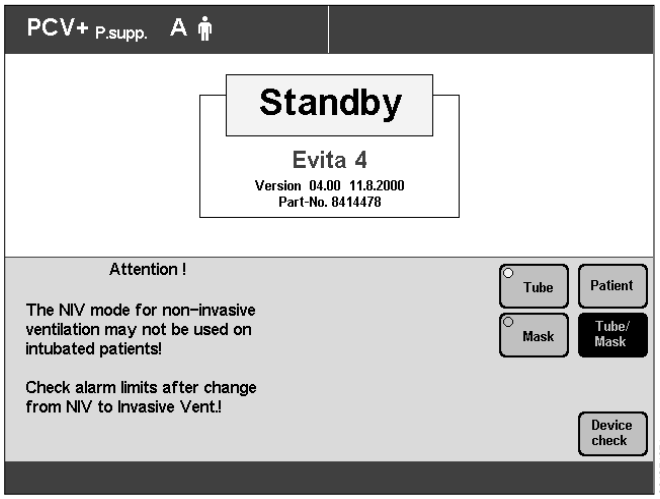
NOTE: Automatic tube compensation (option ATC) that might have been activated during »**Tube**« application mode is without effect in »**Mask**« application mode

Selecting »Mask« Application Mode

may be selected at time of start-up or during operation.

Evita 4

- Switch ventilator to standby using the » ⏻ « key.
- Touch »**Tube/Mask**« screen key.
- Touch »**Mask**« screen key and confirm with dial knob, the yellow "LED" in the screen key is now lit.
- The mask symbol is now showing in the status bar instead of the tube symbol. The background color of the status page will switch from blue to green.



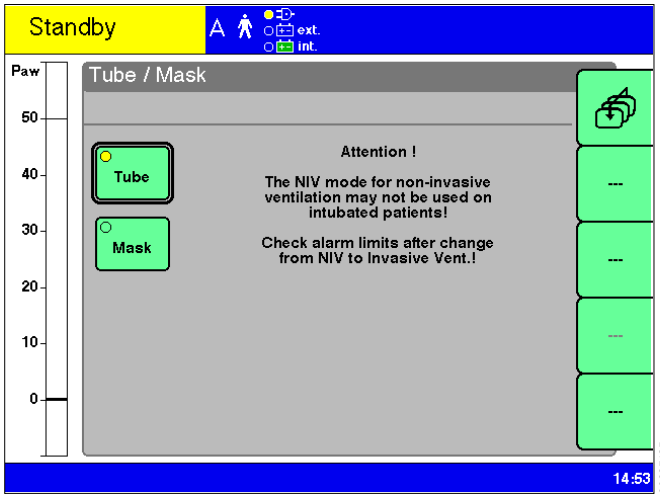
Evita 2 dura

- Switch ventilator to standby by pressing the » ⏻ « key for approximately 3 seconds.
- Mute audible alarm with the »**Alarm Reset**« key.
- Press »**Tube/Mask**« key.

The "Tube/Mask" menu will appear.

- Turn dial knob to select »**Mask**« screen key.
- Press dial knob to confirm.
- **NIV** will appear in the status display.

  The background color of the status page will switch from blue to green.



Setting Ventilation Parameters

- Perform in the same fashion as in »**Tube**« application mode.

For CPAP/PS, an additional screen dial »**Tinsp**« appears on screen.
The ventilator limits the maximum duration of a pressure support breath to 4 seconds in »**Adult**« patient mode and to 1.5 seconds in »**Pediatric**« and »**Neonatal**« patient modes.

- Use Tinsp screen dial to set the limit of pressure support breaths.

NOTE: »**Tinsp**« will also limit the duration of pressure supported breaths in other ventilation modes combined with PS.

Monitoring in »Mask« Application Mode

The following alarms may be switched off in order to avoid alarms caused by artifacts.

– **MV** lower alarm limit for minute ventilation
– **VTi** upper alarm limit for inspiratory tidal volume
– **Tapnea** upper alarm limit for apnea monitoring (delay time).

WARNING !

Switch off alarms only when patient safety is not compromised by deactivated alarms. The operator of the ventilator must still assume full responsibility for proper ventilation of the patient.

To switch off an alarm (example **MV**):

- Decrease »**MV** « until a screen message appears: **»MV off? Confirm with and continue dialing«.**
- Press dial knob to confirm.
- Continue turning dial knob until dashes (––) appear in the display,
- Press dial knob to confirm.

Whenever an alarm limit has been switched off, this is indicated by a permanent advisory message in the alarm display area.

When switching to »Tube« application mode, the ventilator will automatically select the configured default alarm limits
For the alarm limit of PAW (airway pressure low) a delay time »**TDisconnect**« in the range of 0 to 60 seconds may be set.

The following alarm messages are not displayed in »Mask« application mode

- **P. supp. > 4 s**
- **P. supp. > 1,5 s**
- **P. supp. > Tinsp**
- **Leakage**

WARNING !

Always check alarm limits when switching from »Mask« to »Tube«!

Leak Compensation in »Mask« Application Mode

For the purpose of patient triggering, Evita 4 and Evita 2 dura compensate leaks according to the selected patient mode up to the following values:

Adult: 30 L/min

Pediatric: 15 L/min

Neonatal: 7 L/min

The ventilators compensate calculated leaks (independent of patient mode) up to 200 % of the set tidal volume or a maximum of 2 L.

Troubleshooting

Alarm messages in the alarm display field are displayed in hierarchical order.
For example, if two faults are detected simultaneously, the more urgent of the two is displayed.

The priority level of the alarm messages (see Evita 4 sw 4.n and Evita 2 dura sw 4.n Operating Manuals for definitions) is identified by exclamation marks:

Warning = **!!!** Message with top priority

Caution = **!!** Message with medium priority

Advisory = **!** Message with low priority

In the table below, **only messages specific to the NIV application mode are listed**.

This table is intended to help identifying possible causes of an alarm and to assist with prompt corrective action.

Message		Cause	Remedy
Apnea alarm off	**!**	Apnea monitoring has been switched off.	Adjust upper alarm limit of apnea delay time back to the desired value.
MV low alarm off	**!**	Monitoring of lower alarm limit for MV has been switched off	Adjust alarm limit MV ▼ back to the desired level of monitoring.
VT high alarm off	**!**	Upper alarm limit for inspiratory tidal volume V_{Ti} ▲ has been switched off.	Adjust alarm limit V_{Ti} ▲ back to the desired alarm threshold.

WARNING !

For a complete listing of all alarm messages, refer to the respective troubleshooting tables in the Evita 4 sw 4.n and Evita 2 dura sw 4.n Operating Manuals.

Ordering Information

Name/Description	Order No.
Kit "Non-invasive Ventilation NIV"	84 14 474

These Instructions for Use apply only to **Evita 4 or Evita 2 dura** with Serial No.:
If no Serial No. has been filled in by Dräger, these Instructions for Use are provided for general information only and are not intended for use with any specific machine or device.

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